

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE**

CHILDREN'S HEALTH DEFENSE and)
AMY MILLER.)
)
Plaintiffs,)
)
v.)
)
FOOD & DRUG ADMINISTRATION, and)
JANET WOODCOCK, Acting Commissioner of)
Food and Drug Administration,)
)
Defendants.)
_____)

**PLAINTIFFS' MOTION FOR STAY OF THE FOOD & DRUG ADMINISTRATION'S
BIOLOGIC LICENSE FOR PFIZER'S COMIRNATY COVID-19 VACCINE**

**Amended Declaration of LCDR Mark P. Zito, USN
In Support of Children's Health Defense and Amy Miller**

I, LCDR Mark P. Zito, USN, declare:


1. I am over 18 years of age and am competent to testify in this matter.
2. All of the statements made in this declaration are true to the best of my own personal knowledge.
3. I am currently a service member in the US Navy, in the rank of Lieutenant Commander, assigned to Assault Craft Unit 4 on Joint Expeditionary Base Little Creek/Fort Story, VA.
4. I am LCDR Mark P. Zito, and I make this declaration in support of Children's Health Defense's and Amy Miller's motion for stay of the FDA biologic license for Pfizer's Comirnaty COVID-19 vaccine. I began my career at the US Naval Academy and graduated in 2009 with a B.S. in History. Following graduation, I served aboard four ships in four different locations and went on three deployments to Central/South America, the Western Pacific, and the North Atlantic. I also

hold a Master's of Engineering from Cornell University in Operations Research and Information Engineering, and am trained as a nuclear operator working onboard aircraft carriers.

5. I have not been directly confronted about taking the vaccine; however, my choice to not take the vaccine has resulted in significant discrimination towards myself and my comrades. In July, we, the un-vaccinated, were issued N95 masks for mandatory wear. I bought KN95 masks but these are not much of an improvement. In August, un-vaccinated sailors were further restricted to their quarters and limited social function per HPCON C measures. These emails are included in my submission. I know the members sending the emails had nothing to do with the decisions made.
6. If I refuse to get vaccinated and do not get a waiver, I will be subject to the full weight of the UCMJ per the Secretary of Defense's memo dated 24AUG21. Regardless of the waiver status, I expect to lose my livelihood-but this is the hill to lose it on.
7. I intend to submit my religious exemption upon SURFLANT's deadline. The deadline is 10 days after we signed a "Page 13" counselling form. My day is 17SEP21. I initially declined to sign the form; however, today (13SEP21), my Commanding Officer pulled me into his office to discuss. He said the order for 10 days is legal per his conversation with SURFLANT. I expressed that this was not enough time to put together the paperwork for a package. He annotated on the form that I had been informed that I had 10 days to submit my exemption and I initialed. I do not believe that my Commanding Officer intends to artificially tighten the timeline. The form came from SURFLANT. I recorded this conversation.
8. To this point in time, the only discrimination I've received was noted in line 5. Notably, I am senior enough that no one would personally try to intimidate me. Professional decorum plays a larger role in my interactions with senior officers. The amount of mental space the vaccination policies have taken from myself and my comrades is significant. Because the Navy seems to be holding off on making real decisions on the outcome of our personal medical decisions, our minds have become our own worst enemies. I believe this is the worst intimidation a fellow service member could possibly levy on their brothers and sister in arms-how are we to feed our families, how long until we are discharged in any capacity? While the personnel managers and public affairs people are determining the impact of losing a significant portion of Sailors, those same sailors are left to languish in their own thoughts.

9. I have been specifically told that the vaccines are equivalent and that the legal argument that the vaccines are distinct is invalid via memorandum from BUMED.
10. I have not had COVID and do not carry the anti-bodies.
11. I am not pregnant. My wife and I would like to continue expanding our family. To my knowledge, there is no data on fertility impacts to men.
12. I have not received any threats.
13. The BUMED document referenced in LINE 9 is attached.

I declare under penalty of perjury of the laws of the United States of America that the foregoing is true and correct. I executed this declaration on September 23, 2021.


Mark Paul Zito, Jr.



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH VA 22042

EXHIBIT 16

IN REPLY REFER TO
6300
Ser M00/21M00035
3 Sep 21

MEMORANDUM FOR COMMANDER, NAVAL MEDICAL FORCES ATLANTIC
COMMANDER, NAVAL MEDICAL FORCES PACIFIC
COMMANDER, NAVAL MEDICAL FORCES SUPPORT
COMMAND

Subj: INTERCHANGABILITY OF FOOD AND DRUG ADMINISTRATION-APPROVED
PFIZER-BIONTECH VACCINE COMIRNATY® AND FOOD AND DRUG
ADMINISTRATION-AUTHORIZED PFIZER-BIONTECH VACCINE UNDER
EMERGENCY USE AUTHORIZATION

Ref: (a) Comirnaty® Biologics License Application
(b) Emergency Use Authorization for Pfizer-BioNTech COVID-19 vaccine of
23 Aug 2021

1. Purpose. Address the interchangeability of the Food and Drug Administration (FDA)-approved Comirnaty® and FDA-authorized Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) vaccine.

2. Background. On 23 August 2021, the FDA approved the Biologics License Application submitted by Pfizer-BioNTech for individuals 16 years of age and older, reference (a). On the same day the FDA revised the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine for individuals 12-15 years of age and for a third dose in immunocompromised individuals, reference (b).

3. The FDA-approved vaccine, and the vaccine used under the EUA, have the same formulation, and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Navy medical providers can use Pfizer-BioNTech doses previously distributed under the EUA to administer mandatory vaccinations.


B. L. GILLINGHAM

Copy to:
COMPACFLT
COMUSFLTFORCOM
OPNAV (N5)
HQMC HS

Off Installation	
Not Vaccinated	<p>Prohibited from:</p> <ul style="list-style-type: none"> - RECREATIONAL SWIMMING POOLS, GYMS, FITNESS FACILITIES, EXERCISE CLASSES, SAUNAS, SPAS, AND SALONS - TATTOO/BODY ART/PIERCING PARLORS - BARBER SHOPS, HAIR OR NAIL SALONS, AND MASSAGE PARLORS - CINEMAS/THEATERS - PARTICIPATION IN TEAM/ORGANIZED SPORTS - DINE-IN RESTAURANTS (TAKE-OUT AUTHORIZED), BARS, NIGHT CLUBS, CASINOS, CONFERENCES, SPORTING EVENTS, CONCERTS, PUBLIC CELEBRATIONS, PARADES, PUBLIC BEACHES, AMUSEMENT PARKS OR OTHER EVENTS DESIGNED TO PROMOTE LARGE GATHERINGS, TO INCLUDE INDOOR RELIGIOUS SERVICES - OUTDOOR RECREATION WHERE COMMON USE FACILITIES ARE USED AND IF A MINIMUM OF SIX FEET PHYSICAL DISTANCING CANNOT BE MAINTAINED - NON-ESSENTIAL COMMERCIAL RETAIL ESTABLISHMENTS AND SHOPPING MALLS <p>Authorized:</p> <ul style="list-style-type: none"> - USE OF MASS TRANSIT (BUS, RAIL, OR FERRY) - AUTO REPAIR, MAINTENANCE, AND ANNUAL INSPECTION - CURB-SIDE AND DRIVE THROUGH SERVICES - IN-HOME DOMESTIC SERVICES (HOME MAINTENANCE/REPAIR AND LAWN SERVICES) - BANKING SERVICES - PET CARE AND VETERINARY SERVICES - POST OFFICE - LAUNDRY SERVICES, DRY CLEANING - IN-RESIDENCE SOCIAL GATHERINGS THAT INCLUDE MORE THAN TEN (10) GUESTS THAT DO NOT RESIDE IN THE RESIDENCE <p>Other:</p> <ul style="list-style-type: none"> - MEMBERS MAY ATTEND RELIGIOUS SERVICES AND PLACES OF WORSHIP PROVIDED THEY COMPLY WITH CDC MITIGATION MEASURES (FRAGORD 20-032)
Immunized	<p>IMMUNIZED SAILORS WILL BE SUBJECT TO INDIVIDUAL RESTRICTIONS NO HIGHER THAN THOSE CORRESPONDING TO HPCON B, REGARDLESS OF THE HPCON STATUS OF THE INSTALLATION TO WHICH THEY ARE ASSIGNED. (NAVADMIN 086/21)</p> <p>CLOSE CONTACTS WHO HAVE BEEN FULLY VACCINATED AND INDIVIDUALS WHO HAVE TESTED POSITIVE IN THE PAST THREE MONTHS DO NOT NEED TO QUARANTINE. (NAVADMIN 110/21)</p> <p>SYMPTOMATIC PERSONNEL REGARDLESS OF IMMUNIZATION STATUS SHALL FOLLOW LOCAL MEDICAL AND CDC GUIDANCE ON WHAT TO DO WHEN YOU ARE SICK. (NAVADMIN 110/21)</p>

On Installation	
All Personnel Regardless of Vaccination Status	<p>In areas of substantial or high community transmission, DoD requires all Service members, Federal employees, onsite contractor employees, and visitors, regardless of vaccination status, to wear a mask in an indoor setting in installations and other facilities owned, leased or otherwise controlled by DoD (NAVADMIN 161/21)</p> <p>HPCON C: LESS THAN 25% OF NORMAL OCCUPANCY IN THE WORKPLACE and Gatherings limited to 10 people</p> <p>THE FOLLOWING ACTIVITIES HAVE BEEN GRANTED EXEMPTIONS FROM THE OCCUPANCY RATES:</p> <ul style="list-style-type: none">- MEDICAL TREATMENT FACILITIES AND EXPEDITIONARY MEDICAL FACILITIES,- NAVY INSTALLATION FIRST RESPONDER UNITS,- FORCES SUPPORTING CRITICAL NATIONAL CAPABILITIES,- NAVY OPERATIONAL UNITS,- COMMAND HEADQUARTERS,- SHIPYARDS,- FLEET READINESS CENTERS,- AND UNITS PROVIDING ESSENTIAL MISSION SUPPORT.- AUTHORITY TO GRANT ADDITIONAL OCCUPANCY EXEMPTIONS IS DELEGATED TO THE RESPONSIBLE NCC, WITH FURTHER DELEGATION AUTHORIZED IN WRITING TO A LEVEL NO LOWER THAN A GENERAL/FLAG OFFICER IN THE GRADE OF O-7, SENIOR EXECUTIVE SERVICE MEMBER (OR EQUIVALENT). (NAVADMIN 086/21) <p>Gyms and installation MWR services will remain open in HPCON C, but will return to a more restrictive posture similar to what was in place previously in HPCON C. 25% occupancy and 100% mask mandate will be in effect regardless of individual immunization status.</p>

Personnel Movement and Travel	
Not Vaccinated	<p>A local PCS move may be executed without a waiver since it does not involve travel outside of the local area.</p> <p>Execution of PCS orders, Navy Service Members traveling to attend formal training, Other Official Travel (Meetings, Conferences, Site Visits, etc.) from or to locations where travel is restricted requires a waiver</p> <ul style="list-style-type: none"> - PCS travel waiver requests shall be submitted for all Service Members with written orders if either gaining or losing command have travel restrictions in place (i.e.*red*). Gaining and losing commands will endorse concurrence or non-concurrence. If both the gaining and losing command concur with the waiver (i.e. waiver is uncontested), the gaining command, at a level no lower than O-6 or civilian equivalent, is delegated the authority to approve travel. All contested waivers will be adjudicated by PERS-4. - Authority to approve or deny travel waivers for Navy Service Members in the case of: (1) official travel in paragraph 4.B., and (2) official training, not associated with a PCS, in paragraph 4.C. is delegated to the echelon 2 commander. The echelon 2 commander may further delegate waiver authority, but no lower than the first O-6 or a civilian equivalent in the chain of command of the Service Member. <p>(NAVADMIN 073/21)</p>
Immunized	<p>Do not restrict mission essential travel by immunized individuals unless unusual conditions call for immunized travel to be restricted (e.g. close contact with a COVID positive greater than 3 months after immunization)</p> <p>(NAVADMIN 073/21)</p>

Mask Guidance	
All Personnel Regardless of Vaccination Status	<p>In areas of high substantial or high community transmission, the DoD requires all Service members, Federal employees, onsite contractor employees, and visitors, REGARDLESS OF VACCINE STATUS, to wear a mask in an indoor setting in installations and other facilities owned, leased or otherwise controlled by DoD.</p> <ul style="list-style-type: none"> - Installation masking requirements shall be determined by the respective Commanding Officer after assessing the current community transmission levels IAW CDC guidance. - Masking requirements shall be communicated by signage, command websites, social media, and other appropriate methods for installations, other facilities, and worksites. - Organizations should consult should with servicing Labor Relations Office for guidance regarding implementation for bargaining unit employees. - Ships/units in port will adhere to shore installation guidance. - Ships/units at sea will be governed by Health Protection measures outlined in the NAVADMIN referenced below. - All DoD personnel should continue to comply with CDC guidance regarding areas where masks should be worn, including within airports. - Personnel coming on to a DoD installation, other facility or workspace who do not have a mask may be provided one by DoD. <p>(DEPSECDEF MEMO DTD 28JUL21) (COMUSFLTFORCOM MSG DTG 012000Z AUG 21) (NAVADMIN 110/21)</p>
Not Vaccinated	<p>Service members, federal employees, onsite contractor employees, and visitors who are not fully vaccinated also need to continue to physically distance consistent with applicable CDC and DoD force Health Protection guidance.</p> <p>(DEPSECDEF MEMO DTD 28JUL21) (COMUSFLTFORCOM MSG DTG 012000Z AUG 21)</p>

ADMINISTRATIVE REMARKS

NAVPERS 1070/613 (REV. 08-2012) PREVIOUS EDITIONS ARE OBSOLETE

SUPPORTING DIRECTIVE MILPERSMAN 1070-320

SHIP OR STATION:

SUBJECT:

☒ PERMANENT ☐ TEMPORARY

COVID-19 Vaccination Administrative Counseling/Warning

AUTHORITY (IF PERMANENT):

BUMEDINST 6230.15B, ALNAV 062/21, NAVADMIN 190/21

1. On 30 Aug 2021 all U.S. service members were mandated to be vaccinated against COVID-19. Your current medical records indicate that you have not been vaccinated against COVID-19.
2. The following information is provided for your consideration:
- a. Your health and safety are the Navy's number one concern.
 - b. The COVID-19 vaccines are safe and effective.
 - c. The threat from COVID-19 is deadly and real.
 - d. Vaccination has proven to be the most effective defense against serious illness caused by COVID-19.
 - e. Healthcare providers are available to discuss your medically related objections/concerns with the COVID-19 vaccines.
 - f. DoD will administer COVID-19 vaccinations consistent with FDA approved dosing schedules and current standards of medical practice.
 - g. Administration of the COVID-19 vaccine is in the interest of national security and protection of the force. Receiving the vaccine helps protect your family and dependents as well as fellow Sailors and Marines and associated DoD civilians.
3. Unless medically or administratively exempt, any refusal to be vaccinated may constitute a Failure to Obey a Lawful Order and may be punishable under the Uniform Code of Military Justice (UCMJ) and/or administrative action for Failure to Obey a Lawful Order (UMCJ, Article 92).

4. The following corrective action is required:

Within 90 days (28 Nov 2021), you will complete receipt of the COVID-19 vaccination using an FDA approved vaccine or, optionally and alternatively, a vaccine authorized under an Emergency Use Authorization. Of note, the Pfizer-BioNTech COVID-19 Vaccine, now marketed as Comirnaty, is a two-shot series. Proof of vaccination is required and must be entered into your medical record.

5. Member must initial all that apply below:

- ☐ I acknowledge the above counseling/warning and understand its contents.
- ☐ I have been informed of my right to submit a statement in response to this counseling/warning (initial one below).
- ☐ I intend to submit a statement. I will submit my statement within 10 days of this date.
- ☐ I do not intend to submit a statement.
- ☐ I intend to seek an exemption as indicated in para. 3 above. My exemption request will be submitted within 10 days of this date.

Commanding Officer

Member's Signature Date/Signed

Witness' Signature Date/Signed

ENTERED AND VERIFIED IN ELECTRONIC SERVICE RECORD:

VERIFYING OFFICIAL RANK OR GRADE/TITLE:

DATE:

SIGNATURE OF VERIFYING OFFICIAL:

NAME (LAST, FIRST, MIDDLE):

SOCIAL SECURITY NUMBER:

BRANCH AND CLASS:

FOR OFFICIAL USE ONLY
PRIVACY SENSITIVE 9

ACU4 MASK REUSE INSTRUCTIONS

Due to changes made by CNSL to the mask policy for non-immunized personnel, you have now been issued TWO N95 Masks. Because you have elected to decline the COVID Vaccine or are not past the 14 days after the completion of a vaccine series, you are required to wear a mask. That mask will be a **KN95 or an N95 ONLY**. The N95 or KN95 mask will be worn upon entering any CNSL installation, building, or craft. **It will only be removed upon exiting the CNSL Installation.**

Reuse of N-95 Facemasks

Due to a nationwide shortage of N-95 facemasks, reuse of non-soiled, intact N-95's is expected. Reuse refers to the practice of using the same N-95 respirator for multiple days but removing it ('doffing') after leaving a CNSL installation.

Maximum number of uses: A single clean, intact N-95 can be used up to 5 days.

Storage: Hang used respirators in a designated storage area or keep them in a clean, breathable container such as a paper bag between uses. To minimize potential cross-contamination, store respirators so that they do not touch each other and the person using the respirator is clearly identified. Storage containers should be disposed of or cleaned regularly.

When NOT to reuse an N-95 Facemask:

- Discard N95 respirators following use during aerosol generating procedures (ex: intubation).
- Discard N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
- Discard N95 respirators following close contact with any patient co-infected with an infectious disease requiring contact precautions.
- Discard N95 respirator if the mask becomes damaged, soiled or difficult to breathe through, it should be removed from circulation and disposed following local protocols.

Mask Replacement

- Masks will be re-issued every 10 days and they will be signed for.
- If a mask becomes unserviceable, **DO NOT** dispose of it. Bring it to medical for a One-for-one swap.
- If the mask is lost, you must fill out a DD200 and route it through your Department Head and back to the Medical department.
- Do not lose or forget your mask.

A mask will no longer be required 14 days after you have completed your COVID vaccine series.

How to Get Vaccinated:

- **STEP ONE:** Log Into the DHA Appointing Portal (DAP) at: <https://informatics-stage.health.mil/COVAX/>
- **STEP TWO:** Open the enclosed User Guide for navigating the DHA Appointing Portal (DAP); this guide walks you through each step to book an appointment with screenshots included as visual aids. **The user guide uses a different mil base and MTF as an example. Please follow these instructions for our AOR: Select "VIRGINIA" → Select appropriate MTF base ("Joint Expeditionary Base Little Creek") → Select auto-populated MTF for that base ("NMRTU Boone").**
- **STEP THREE:** Schedule your second dose at the same time.
- **STEP FOUR: BE A GROWN AND RESPONSIBLE ADULT AND DO NOT MISS YOUR APPOINTMENTS!**

Or

- By going to your nearest local pharmacy and getting the vaccine and bringing the documentstion back to the medical department for inclusion into your record.